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EXAMINER

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ART UNIT PAPER NUMBER

1638

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22

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/140,886

Applicant(s)

Wilson

Examiner

Fox

Group Art Unit

1638

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

P r i d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 4/7/02
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-22 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-22 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Applicati n Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

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The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's amendment of 7 January 2002 and accompanying arguments have overcome the following rejections of record: the rejections of claims 1-22 under 35 USC 112, second paragraph, as set forth on the paragraph bridging pages 7 and 8 of the last office action and as set forth in the first two full paragraphs of page 8 of the last office action; and the rejection of claims 1-22 under 35 USC 103 as set forth on page 9 of the last office action.

Claims 1-22 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as stated on pages 2-3 of the last office action.

Claims 1-22 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, as stated on page 5 of the last office action.

Applicant is also directed to Holl et al and Kamra et al who teach the unpredictability inherent in the transfer and maintenance of uncharacterized DNA in transformed plant cells and plants. Holl et al teach that uncharacterized pea DNA was not maintained in progeny of transformed plants, and that other workers' allegedly successful results have not been replicated (see, e.g., page 171, Abstract; paragraph bridging pages 171 and 172; page 174, penultimate

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paragraph; page 175, first two full paragraphs). See also Kamra et al who teach that uncharacterized bacterial DNA was quickly degraded in lettuce plants grown from seeds treated therewith (see, e.g., page 986).

Claims 1-22 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, regarding the recitation of "uncharacterized" in claims 1 and 15, as stated on page 7 of the last office action.

Claims 1-2 and 8-9 remain rejected under 35 U.S.C. 102(b) as being anticipated by Masoud et al, as stated on page 8 of the last office action.

Claims 1-2 and 8-9 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 299,552 (SOLVAY).

The claims are drawn to a method for obtaining a transgenic plant comprising transforming recipient plant cells with uncharacterized DNA from a donor plant species contained in a vector, selection of transformed cells and plants, harvesting seed therefrom, growing plants from the seed, and selecting plants having improved agronomic characteristics; and the resultant plants.

SOLVAY teaches a method for transforming recipient barley plant embryo cells with a vector comprising a multifunctional linker, a selectable marker gene, and uncharacterized wheat donor DNA for the transfer of the agronomic characteristic of high baking quality, wherein plants are produced from the resultant transformed cells, and wherein seeds are produced on the self-

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pollinating crop; and also teaches a method for transforming recipient wheat embryo cells with a vector comprising a multifunctional linker, a selectable marker gene, and uncharacterized barley donor DNA for the transfer of the agronomic characteristic of disease resistance, wherein plants are produced from the resultant transformed cells, and wherein seeds are produced on the self-pollinating crop (see, e.g., pages 3-6, 8 and 11).

Claims 1, 4, 8 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Korohoda et al.

Claims 4 and 11 are drawn to a method of plant transformation further comprising selfing the selected plants and harvesting the resultant seed, and the plants produced thereby.

Korohoda et al teach a method for transforming recipient maize subspecies *saccharata* embryo cells with uncharacterized DNA from a maize donor subspecies *indurata*, wherein the donor subspecies exhibits the agronomic trait of fully filled kernels, followed by selection of the transformed cells based upon the morphology of the kernels, followed by production of transformed plants from the transformed kernels, followed by selection of transformed plants which exhibit improved agronomic characteristics (filled kernels and/or male sterility), followed by selfing of the transformed plants and harvesting the resultant seed (see, e.g., paragraph bridging pages 95 and 96; pages 96-98).

Claims 1, 4, 6, 8, 11 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Zhou et al.

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Claims 6 and 13 are drawn to a method of plant transformation further comprising utilizing the selected plants in a plant breeding program involving subsequent generations of crossing, progeny production, and selection for improved agronomic traits; and the resultant plants.

Zhou et al teach a method for transforming embryo cells of a recipient cultivated cotton species with uncharacterized DNA from a wild cotton donor species which exhibits disease resistance, followed by selection of transformed plant cells and plants based upon their disease reaction, followed by several generations of selfing to produce seed and plants therefrom, wherein each generation of progeny is selected for the improved agronomic trait of disease resistance (see, e.g., page 240, penultimate paragraph; pages 242-246). Zhou et al also teach a method for transforming embryo cells of a recipient *Gossypium hirsutum* with uncharacterized donor DNA from *G. barbadense* or *G. thuberi*, wherein transformed plants were selected with the improved agronomic traits of improved fiber quality and yield or shorter maturation, respectively (see, e.g., page 247). Zhou et al also teach a method for transforming embryo cells of a recipient *G. barbadense* with uncharacterized DNA from an *Abutilon avicennae* donor, wherein transformed plants were selected with the improved agronomic traits of improved fiber quality and yield (see, e.g., page 247, bottom paragraph).

Claims 1, 4, 6, 8, 11 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Soyfer et al in light of Turbin et al.

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Soyfer et al teach a method of transformation of recipient barley embryo cells of a plant producing mutant starch with uncharacterized DNA from a donor barley variety whose plants produce wild-type starch, followed by selection of the transformed cells and plants produced therefrom on the basis of wild-type starch, followed by generations of selfing to produce seeds and progeny plants which are also selected for the agronomic trait of improved starch (see, e.g., page 226, column 2; pages 227-231). Soyfer et al state on page 226, column 2, first full paragraph, that the specific method of transformation was that taught earlier by Turbin et al (see, e.g., Turbin et al, paragraph bridging pages 60 and 61; pages 61-64; page 66).

Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 299,552 (SOLVAY).

The claims are drawn to methods for plant transformation further comprising backcrossing or selfing the transformants to produce further generations of progeny which can be selected for desirable traits and incorporated into breeding programs, the use of vectors comprising a selectable marker gene bounding each end of the uncharacterized DNA, and the use of corn/sorghum crosses.

The teachings of SOLVAY have been summarized above. SOLVAY does not explicitly teach the use of selfing or backcrossing of the resultant selected transformed plants, the use of more than one selectable marker, or the use of corn/sorghum crosses.

It would have been obvious to one of ordinary skill in the art to utilize the method of transforming a recipient cereal species with DNA from a different donor cereal species contained

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in a vector comprising a selectable marker gene for the introduction of agronomic traits thereto, as taught by SOLVAY, and to modify that method by incorporating known breeding methods such as backcross breeding or selfing, other cereal species such as maize or sorghum, and more than one selectable marker gene; given the recognition by those of ordinary skill in the art that each would have been expected to perform in its known and expected manner, and given the recognition by those of ordinary skill in the art that choice of number of marker genes or cereal species to be transformed would have been the optimization of process parameters.

No claim is allowed.

Applicant's arguments filed 7 January 2002, insofar as they pertain to the rejections above, have been fully considered but they are not persuasive.

Applicant urges that the written description rejection and enablement rejections are improper, given the teachings of the Wilson and Stine declarations submitted on 20 February 2001. Applicant further argues that the absence of regulatory DNA on the uncharacterized DNA fragment will not result in the production of plants with improved agronomic characteristics (page 4 of the response, top paragraph).

The Examiner maintains that the Wilson declaration demonstrates the obtention of corn plants transformed with the uncharacterized sorghum DNA bounded by two selectable marker genes, as evidenced by the expression of those non-sorghum marker genes; while the Stine declaration merely opines that techniques are available for identifying and evaluating transformed plants and their progeny containing exogenous uncharacterized DNA and exhibiting improved

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agronomic traits. However, neither declaration demonstrates that the exemplified uncharacterized sorghum DNA actually conferred any trait, improved or otherwise, to the recipient maize plants.

Furthermore, neither declaration addresses the deficiencies set forth in the written description rejection, namely, that the specification does not adequately describe even the exemplified “uncharacterized DNA” from sorghum in terms of its sequence or genes present, that the specification does not identify any structural features of the “uncharacterized DNA” which would be responsible for its alleged (and unproven) function of conferring improved agronomic traits, and that the specification clearly does not demonstrate reduction to practice of any other “uncharacterized DNA” from any other donor plant species which would confer improved agronomic characteristics to a recipient plant. Given the single disclosure of an “uncharacterized DNA fragment” from a single plant species; the breadth of the claims which encompass any donor plant species from a multitude of unrelated species, genera, and families; and the lack of guidance as discussed above and previously; the specification does not provide an adequate written description of the genus as broadly claimed so that one skilled in the art would recognize Applicant to have been in possession of the claimed invention. See *University of California v. Lilly* cited previously.

Regarding the enablement rejection, the Examiner maintains that the mere demonstration of integration of the “uncharacterized donor DNA” by the Wilson declaration does not remedy the unpredictability inherent in the expression of uncharacterized foreign DNA in cells of heterologous plant species, as set forth in previous Office actions. In addition, the

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unpredictability inherent in the maintenance of large stretches of "uncharacterized donor DNA" from heterologous or homologous species, when introduced into plants by a multitude of non-exemplified methods, as evidenced by Holl et al and Karma et al, has not been addressed by either declaration. The allegations of the Stine declaration are insufficient to overcome the evidence of unpredictability set forth by the Examiner in the form of scientific reasoning and publications. Applicant's admission of this unpredictability, regarding the necessity of native regulatory sequences on the "uncharacterized DNA", is noted above.

Applicant urges that "uncharacterized" is not indefinite because it has an art-recognized meaning. The Examiner maintains that the specification is silent with respect to the definition of this term, and that no other evidence of its art-recognized definition has been presented.

Applicant urges that the rejection of the claims as being anticipated by Masoud et al is improper, given the failure of the reference to employ "uncharacterized" DNA. The Examiner maintains that the reference employs DNA which has not been characterized in terms of linker sequences or signal sequences which would be part of the DNA transferred into the recipient plant cells. Furthermore, the length or sequence of the rice gene was not characterized.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (703) 306-3218. The fax phone number for this Group is (703) 872-9306. The after final fax phone number is (703) 872-9307.

March 19, 2002

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180-1638

